

Using Statistical Quality Control Techniques to Monitor Blood Glucose Levels

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Continuous Quality Improvement techniques developed in industry are increasingly being applied to the medical field. Statistical process control charts are a CQI technique aimed at monitoring a process and its variability. At our hospital, statistical quality control charts are being constructed from laboratory blood glucose measurements of patients receiving enteral or parenteral nutrition. The charts will be used to monitor glucose levels, reveal variations, and illustrate the effects of new protocols designed to manage glucose levels.

INTRODUCTION

Amid increasing pressure to reduce the cost of health care while maintaining or enhancing the quality of the care delivered, some in the medical field have turned their attention to Continuous Quality Improvement (CQI) techniques developed in industry.¹⁻¹² One area of CQI focuses on "efforts to continuously increase knowledge of and control over variation in the processes of work through the widespread use of scientific methods of data collection and analysis and action on data".^{10,11} This objective is the aim of a body of methods known as Statistical Quality Control (SQC).^{13,14} The guiding principle of SQC (and CQI in general) is that it is the work "process", and not the individuals participating in the process, that must be analyzed, measured, and modified in order to improve quality. Quantifiable process variables or outcomes must first be identified, and then regularly measured. Improving quality stems directly from reducing variation in these variables or outcomes. SQC provides techniques for charting and analyzing the variables or outcomes.

SQC methods generally utilize small sample groups selected from a process at regular time intervals, for example, four doorknob diameter measurements taken from a doorknob assembly line each day. To construct an "X-bar" chart, the means of the groups of four diameter measurements would be plotted against time. A center line reflecting the mean of the group means is also plotted. Finally, upper and lower control limits representing 2 or 3 standard errors about the centerline are plotted. An example of an X-bar chart is shown in Figure 1.

After constructing the chart, before ever concerning himself with reducing variability in the

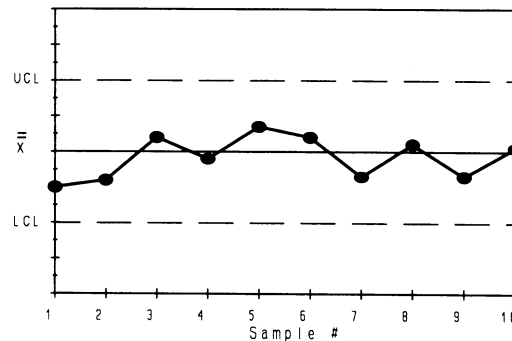


Figure 1 An example of an X-bar chart

process, the investigator first determines whether or not the process is "in control". The process is *not* in statistical control if any plotted mean falls outside the upper or lower control limits or if the data exhibit "trends", "runs", "periodicity", or "hugging of the center line". These tendencies are defined in the literature.¹³⁻¹⁶ They indicate that non-random variations are occurring in the process. SQC dictates that investigations be made to determine the cause of the non-random variations and then that corrective actions be taken. If the data do not exhibit any non-random behaviors, then the process is said to be "in control", or "stable", i.e., any variation in the measurements is due only to random variation.

X-bar charts are usually used in conjunction with either R (range) charts or S (standard deviation) charts. R and S charts are constructed in the same manner as X-bar charts, except the summary statistic plotted is range or standard deviation of the sample group instead of the mean. The chart's center line represents the mean of the ranges or the mean of the standard deviations. SQC recommends that the R or S chart be examined first for non-random variation. Once non-random points on the R or S chart are identified and addressed, non-random variation in the X-bar chart may appropriately be addressed. Then, after non-random variation is eliminated from both charts, the task of reducing variability is undertaken.

A P chart displays the proportion of the group conforming to a certain criterion, over time. For example, each point on a P chart may represent the proportion of doorknobs that were defective in a day.

Computers make the task of gathering and storing

the data necessary to construct charts more convenient and less time-consuming. Software packages make chart construction and analysis much easier than the tedious manual construction and analysis that would otherwise be required.

At LDS Hospital, we wanted to know how glucose levels of patients receiving enteral feedings and Total Parenteral Nutrition (TPN) were varying both between patients and over time. Glucose variation is due primarily to four factors: (1) glucose infusion rates, (2) exogenous insulin rates, (3) exogenous use of other glucose-influencing hormones (steroids, glucagon, catecholamines, and growth hormones), and (4) patient factors such as stress, diabetes, liver function, and electrolyte abnormalities. Of these four factors, the healthcare provider can control or compensate for (1), (2) and (3), but has less control over (4), except for controlling electrolyte balance. However, we had the perception that there was wide variability in the manner (1), (2), and (3) were being controlled, and that this variability at least in part was responsible for clinically unacceptable glucose levels in the patient population in question. Our hope was that if we could in a systematic way control the factors we *could* control, we could compensate for the derangements caused by the factors we *could not* control. The expected result would be glucose values in the TPN-fed and enterally-fed population that were more clinically acceptable. SQC charts would enable us to observe that result, first in the disappearance of most or all of the "out-of-control" points, and then later in a reduction in the variability of glucose values.

This report focuses on our application of SQC control charts to monitor a "process". In the medical quality assurance literature, "process" refers to the "set of activities that go on within and between practitioners and patients".⁴⁻⁶ Our "process" in this case is the management of patients' glucoses.

METHODS

Each night, just after midnight, a glucose monitor is run on LDS Hospital's Health Evaluation through Logical Processing (HELP) clinical information system. The main feature of the HELP system is a centralized patient database located on a Tandem mainframe computer.¹⁷ The database receives inputs from many departments and ancillary services throughout the hospital.

The glucose monitor first identifies patients who were on the Nutritional Support Service's daily TPN or enteral patient lists. It then searches for laboratory glucose data taken from those patients during the day.

Seven overlapping groupings are formed from the glucose values. The groups are composed of glucose values from: (1) ICU patients, (2) non-ICU patients, (3) patients receiving steroids, (4) patients not receiving steroids, (5) diabetic patients, (6) non-diabetic patients and (7) all patients. Naturally, group (7) is the set of all glucose values. The monitor writes the categorized glucose values out to two Tandem files -- one for the TPN patients, and the other for the enteral patients.

Quarterly, the Tandem glucose data files are downloaded to a personal computer running the SPSS 6.0 for Windows statistical software package. An SPSS syntax script reads the files and does further grouping and analysis. It counts how many glucose values are "above target" (> 200 mg/dl), "below target" (< 100 mg/dl), "above critical" (> 350 mg/dl), and "below critical" (< 60 mg/dl). It then constructs statistical quality control charts. The three standard error level is used in constructing control limits. For each file, 42 control charts (6 charts for each of the 7 patient sub-categories) are generated. The 6 charts are: (1) an X-bar chart, (2) an S chart, (3) a P chart showing the proportion of glucoses above target, (4) a P chart showing the proportion of glucoses below target, (5) a P chart showing the proportion of glucoses above critical, and (6) a P chart showing the proportion of glucoses below critical.

Weeks are used as the sampling intervals in each chart. Each point on an X-bar chart represents the mean glucose value for the week. Each point on an S chart represents the standard deviation of the glucose values observed during the week. In the P charts, each point represents the proportion of the week's glucose values that met the conformance criterion ("below target", "above critical", etc.).

RESULTS

In the interest of space considerations, only three charts will be presented and discussed as illustrative of the analysis process. The X-bar chart and the S chart for TPN patients in the ICUs are shown in Figures 2 and 3 for the period from July 1, 1994 to January 31, 1995. A P chart reflecting the proportion of ICU TPN patient glucoses above target (> 200 mg/dl) is shown in Figure 4, for the same time period.

As per SQC procedure, the S chart will be addressed first, before examining the X-bar chart. Several points in Figure 3 indicate non-random variation in the process. The point outside the control limits at week 4 of 1995 could be brought inside the limits by eliminating one particular patient's data. That patient's glucose values rose to levels above 400

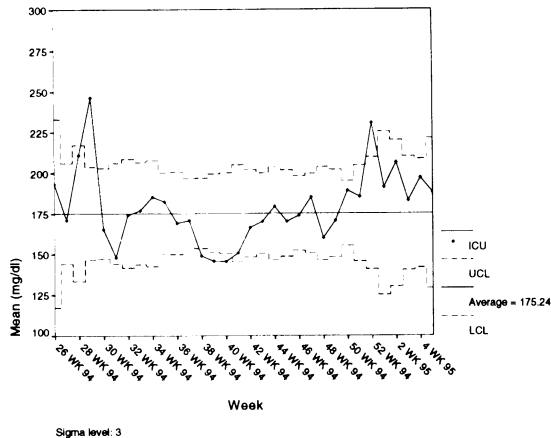


Figure 2 X-bar chart of lab glucose values of TPN patients in the ICUs

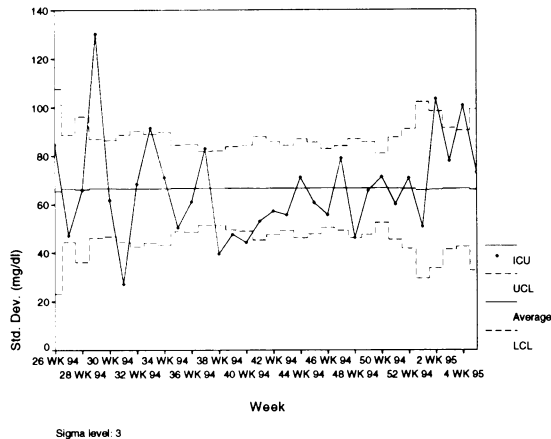


Figure 3 S chart of lab glucose values of TPN patients in the ICUs

mg/dl following surgery on January 22. Similarly, the out-of-control point at week 2 could be brought inside the control limits by eliminating the glucose values of another patient. That patient's glucose level reached a low of 51 mg/dl on January 9, 1995 and a high of 443 mg/dl two days later following surgery. We suspect that the other points indicating non-random variation are similarly attributable to particular patients with especially deranged glucose levels.

We have identified sources of non-random variation, but have not eliminated the causes. Therefore, we are not ready to examine the associated X-chart.

The P chart (Figure 4) exhibits a point outside the control limits at week 52 of 1994. The point can be brought within the control limits by eliminating the

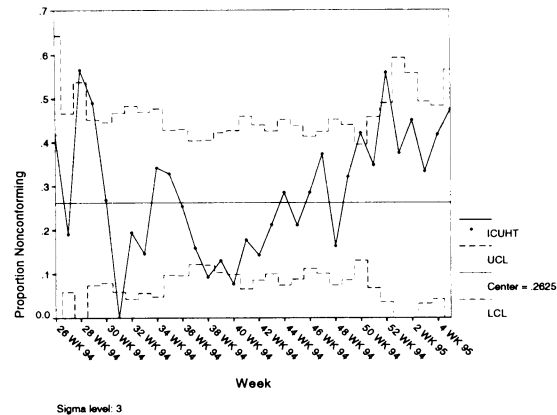


Figure 4 P chart showing proportion of ICU TPN patient glucose measurements that were higher than the target (> 200 mg/dl)

data of two patients who had consistently high glucose measurements during the week (one with a high of 400 mg/dl and the other with a high of 337 mg/dl). Again, we have identified sources of non-random variation, but not yet eliminated their causes.

The points outside the control limits in Figures 3 and 4 indicate that the process of managing the glucose levels of TPN patients in the ICUs varies non-randomly, i.e., the process is unstable. In keeping with SQC procedure, steps are presently being taken to increase the stability of the process. Firstly, a protocol for TPN ordering was implemented on February 1, 1995. The protocol was based on the work of Bistran and McMahon, et. al.¹⁸⁻²⁰ It dictates the maximum dextrose infusion rate to be used, specifies the conditions under which fat calories should be increased, and specifies how much insulin should be included in the TPN order according to how much has been given previously and what current glucose levels are. The protocol currently exists only in paper form and is not yet used consistently. Modifications are still being made to it. Also, a new computerized TPN ordering program will soon be installed. We will be able to use the new program to enforce some parts of the new protocol.

Secondly, a new protocol for administering insulin drips is being piloted in one of the ICUs (the Shock/Trauma/Respiratory ICU) at LDS Hospital. The insulin drip protocol will work in conjunction with the TPN protocol to determine insulin dosages to be administered to TPN patients and as a result hopefully add stability to the process of managing glucoses. An S chart and a P chart illustrating data since February 1, 1995 are shown in Figures 5 and 6.

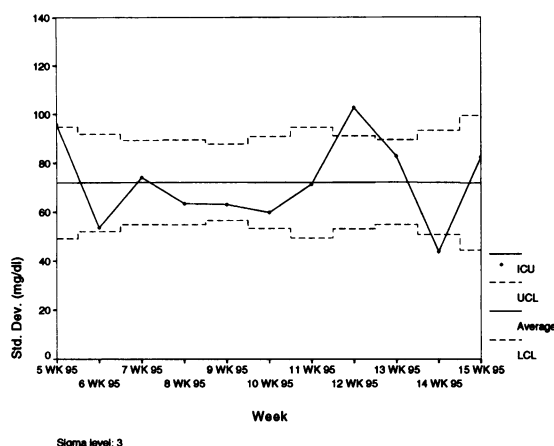


Figure 5 S chart of ICU TPN patient glucose levels after implementation of TPN protocol

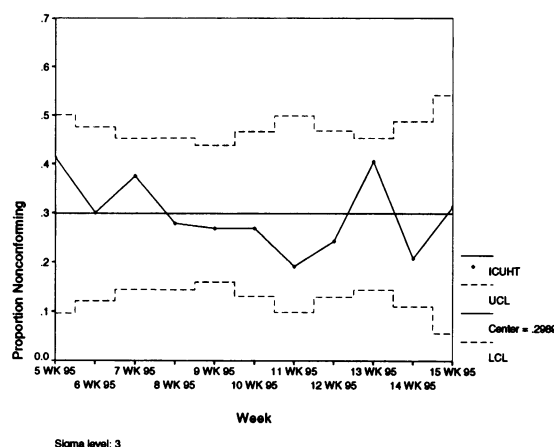


Figure 6 P chart showing proportion of glucoses from ICU TPN patients higher than target (> 200 mg/dl), after implementation of TPN protocol

DISCUSSION

Figure 6 shows no out-of-control points, but it is too soon to conclude stability in the process. SQC theory suggests that at least 20 to 25 measurements be taken. Furthermore, Figure 5 demonstrates that non-random variation still exists in the process. This is not unexpected. As has been noted, the TPN protocol is not yet being used consistently. We expect that a certain education period will be necessary before the TPN protocol is fully complied with. Also as has been noted, work on the protocol is ongoing. The new TPN ordering program will assist with compliance. It will automatically set the dextrose

infusion rate, for example. Other aspects, such as insulin dosages to be ordered, will not be automatically enforced by the program, but reminders to the ordering physician may be included.

The insulin drip protocol has only been in effect since March in only one of the four ICUs in the hospital and education is also probably an issue. We would expect to see observable increases in stability only after the protocols are used consistently.

Our implementation of SQC theory presents several problems. Others have suggested using control charts to monitor physiologic variables in individuals.¹¹ A physician at one of our affiliated clinics is monitoring the glucose levels of individual patients using control charts. In our use of control charts, however, we are grouping multiple patient processes together in our weekly groups. Furthermore, we are adding to our "process" the procedures by which clinicians manage those patient processes. Our process, then, is the sum of multiple patient physiological processes as well as multiple clinician management processes. Hopefully, implementing the TPN and insulin drip protocols will both stabilize the clinician management processes and reduce the variation in them. It remains to be seen whether or not differences between individual patients' physiologies are small enough to allow a completely stable process to result.

Another problem in our graphical analysis is disproportionate weighting of patients within our weekly groups. Unlike in an assembly line setting, where groups may be formed by taking a fixed number of samples from the line each day, we could devise no rational method of sampling only a few glucoses each week. Instead, we are in essence employing 100% sampling, i.e., we are including in our weekly groups all glucose measurements taken during the week. As a result, those patients who have multiple glucose measurements taken during a day exert more influence on the weekly statistic than do patients who have only one or fewer measurements per day. Because patients with more deranged glucose values tend to have more frequent measurements performed, the weekly statistic is likely pulled in the direction of derangements. We tolerate this problem because it is those very derangements that we would like brought to our attention; overweighting only serves to over-emphasize the out-of-control points. We interpret the charts in context, aware that points are weighted toward derangements.

Manual data gathering and control chart construction would be a tedious or even untractable process. The integrated nature of the HELP system allows the necessary data to be gathered by a single

program that runs automatically and unsupervised. The glucose values are available from the data sent to the HELP system from the blood laboratory. ICU versus non-ICU determination is made by comparing glucose measurement times with room trace information stored in the system. Patients receiving steroids at the times of glucose readings can be determined from the drug order information. Diabetic patients can be identified because the Nutritional Support Service staff enter that information in the computer on their problem lists.

We foresee increasing the stability of the glucose management process by standardizing the way insulin and TPN are administered. In so doing, we expect to be able to observe the increased stability on control charts. Certain of the control charts will likely prove more useful than others. As we gain experience, we will reduce the number of charts generated to that most useful subset. At the very least, the use of control charts provides us with a means of visually monitoring glucose levels of patient subpopulations and how the levels are varying over time. Previously, we had only a vague notion of that information.

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